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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,537	12/15/1999	JOHN C. ROYER	4216.260-US	3928
25907	7590	06/20/2005	EXAMINER	
NOVOZYMES BIOTECH, INC. 1445 DREW AVE DAVIS, CA 95616			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/461,537

Applicant(s)

ROYER ET AL.

Examiner

Maria B. Marvich, PhD

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 27 and 28.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.


JAMES KETTER
PRIMARY EXAMINER



Continuation of 11. does not place the application in condition for allowance because:

Applicants traverse the claim rejections under 35 U.S.C. 112, first and second paragraph on pages 3-6 of the amendment filed 5/11/05. Applicants argue that it is clear what is intended by "identifying characteristics" as this term is well known in the art to mean the growth and morphological characteristics of a species or genus of a microorganism. Furthermore, the term has been used in numerous patents. The recited strain is alternatively called ATCC 20334, NRRL 30747 and IMI 145425 and was mistakenly classified as *Fusarium graminearum*. As *Fusarium graminearum*, the growth and morphological characteristics of the host cell is characterized by various features relating to conidia, cell shape, conidophores etc (see e.g. page 5, line 24 – page 6, line 6). Applicants argue that the ATCC catalog references US 3,937,654, which discloses the morphological and growth characteristics of ATCC 20334 in col 2, lines 2-44. Taken together, applicants argue that the specification and US 3,937,654 provide the identifying growth and morphological characteristics. Finally, applicants argue that the identifying characteristics associated with strain ATCC 20334 (NRRL 30747) have not changed just the species name and therefore the characteristics recited in the specification are the identifying characteristics of ATCC 20334. Rather, the characteristics are inherent to the strain.

Applicants' arguments filed 5/11/05 have been fully considered but they are not persuasive. The instant claims recite use of a host cell to be recognized as appropriate host cells by having the "identifying characteristics" of NRRL 30747. Despite the confusion as to whether instant specification is describing *Fusarium graminearum* or *Fusarium venenatum*, there is no definition or explicit description as to what is intended by "identifying characteristics" of the recited strain. Applicants have indicated where in the specification and in US 3,937,654 the growth and morphological characteristics of ATCC 20334, NRRL 30747 and IMI 145425 can be found. By this description, it appears that applicants intend the growth and morphological characteristics outlined in the specification on page 5, line 24 – page 6, line 6 or in US 3,937,654 in col 2, line 2-44 to be the "identifying characteristics". Therefore, applicants appear to argue that a definition of "identifying characteristics" is inherent in the specification and in US 3,937,654. By so doing, applicants would like to rely on descriptions of the invention that are not reasonably applied to the claims as written. "Identifying characteristics" is a broad and diverse term- is one characteristic adequate to identify the host cell, two, three? The overlap between the two sets of growth and morphological characteristics provided in the specification and US 3,937,645 is unclear. Does an identifying characteristic of the recited host cell need to be all of the two sets of characteristics or any characteristics that is in common between the two or any single characteristics in either? "Identifying characteristics" is a broad and diverse designation for which neither the specification nor the prior art prescribes a standard meaning. Hence the specification lacks appropriate written description of the "identifying characteristics" of the recited host cell. Furthermore, as to the patentability of the instant case in light of similar claims in published patents that possess similar disclosures, rejections based upon this argument have been addressed in *re Giolito and Hoffman*. "It is immaterial whether similar claims have been allowed to others" (see in *re Giolito and Hoffman* 188 USPQ 645). Rather, each application is reviewed on its own merits.

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

Application No.

09/461,537

Examiner

Maria B. Marvich, PhD

Applicant(s)

ROYER ET AL.

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

The amendment document filed on 11 May 2005 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: The claims are indicated as previously amended but have been previously amended.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.